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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 225,904	01 05 1999	DAVID SIDRANSKY	07265 061002	1766

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EXAMINER

SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 12 14 2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.
09/225,904

Applicant(s)
Sidransky

Examiner
Jehanne Souaya

Art Unit
1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Oct 10, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Oct 10, 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

4. ☐ Applicant's reply has overcome the following rejection(s):
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attachment
7. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
- Claim(s) allowed: none
- Claim(s) objected to: none
- Claim(s) rejected: 1-11

This communication was prepared by the Examiner

Other

ATTACHMENT

1. Applicants arguments have been thoroughly reviewed but were found unpersuasive to place this application in condition for allowance. Applicants traversal of the rejection of claims 1-3, 5, and 7-11 under 35 USC 112/2nd paragraph with regard to administration of a "poison" were found persuasive. Consequently, this rejection has been withdrawn. Applicants traversal of the rejection of claims 1-11 made under 35 USC 112, first paragraph have been fully considered but were found unpersuasive. The response traverses that in view of the Stolberg reference one skilled in the art viewing the specification would have known that a gene therapy method reasonably would be expected to be useful for treating a cell proliferative disorder associated with expression of a 5' ALT polynucleotide. This argument has been thoroughly reviewed but was found unpersuasive. Firstly, the specification provides no description or working examples of a method of gene therapy to treat a cell proliferative disorder, let alone *any* cell proliferative disorder. The specification provides no teaching or working examples of a reagent (any reagent) that modulates expression of 5' ALT to treat any cell proliferative disorder. Case law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not to find out how to use it for themselves. In re Gardner 166 USPQ 138 (CCPA) 1970. Further, the Stolberg reference does not overcome these deficiencies in the specification nor does the Stolberg reference provide any guidance to the skilled artisan that would enable the full scope of the broadly claimed invention.

The response further traverses that one skilled in the art, viewing the specification, would have known that a demethylating agent such as 5'deoxyazacytidine can be used to treat a cell

gene. This argument has been thoroughly reviewed but was found unpersuasive as the specification expressly states at p. 65 (2nd full paragraph) "Azacytidine had profound effects on cell growth, morphology, and viability. However these effects were non-specific and observed in cell lines with homozygous deletions of p16 and with retention of p16 alleles *independent of methylation status*. Therefore, we cannot attribute these non-specific effects to re-expression of p16, since other genes might also be affected by azacytidine." (emphasis added). Therefore, the skilled artisan, viewing the specification, would have been taught that the effect of azacytidine was non specific and that the effect was not predictably correlated with altered p16 expression due to methylation of a CpG island in a p16 gene as the effects were observed with retention of p16 alleles independent of methylation status.

With regard to the submission of the Liggett et al reference, see box 7 of the advisory action.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Examiner

Art Unit 3100

Dec 12, 2001

Dec. 12, 2001

7/11/01